Adjuvant therapy with autologous dendritic cell (DC) vaccine based on cancer-testis antigens (CaTeVac) in melanoma patients

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BACKGROUND:

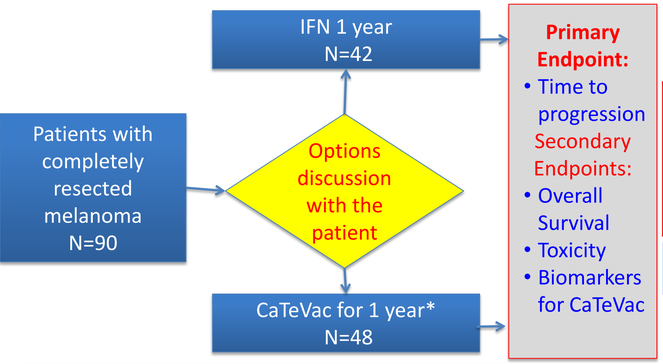
Interferon-alfa (IFN) is still a standard and most widely used adjuvant therapy for patients with skin melanoma. Nevertheless, the efficacy of this approach is doubtful despite decades of clinical trials. CaTeVac is autologous DC, derived from peripheral mononuclear cells of the patient, loaded with lysate of allogenic melanoma cell lines with high expression of cancer-testis antigens. We compared cohort of patients receiving adjuvant therapy with CaTeVac with a cohort of consecutive patients in our center who received IFN in the adjuvant setting. Here we report first survival analysis for this study.

MATHERIALS AND METHODS

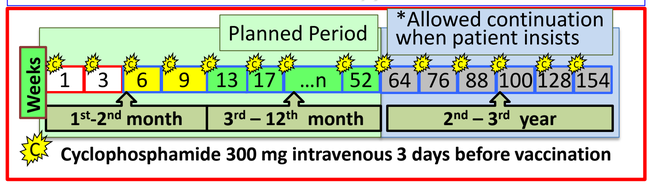
Main Inclusion criteria

- Age>16 y.o.
- Morphologically verified cutaneous melanoma
- Completed radical surgery 45 days before vaccination start
- Signed Inform Consent Form
- Adequate liver, kidney and bone marrow function
- No evidence of uncontrolled comorbidities
- No concomitant immunosuppressive drugs
- No other anticancer therapy allowed

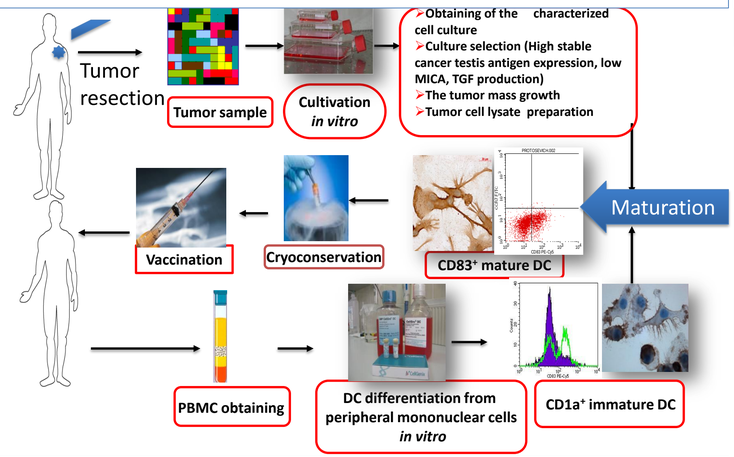
Study design



CaTeVac Therapy Plan



CaTeVac Production



Patient's Characteristics

Characteristic	CaTeVac N=48	IFN N=42	p
Sex: male	47.9%	32%	0.192
Age: mean range	53 16-85	49 23-77	0.205
Ulceration present	59.4%	71.4%	0.444
Nodes positive	93%	75%	0.032
Stage (UICC TNM v.7) I-II III IV	 0 79.2 20.8	 28 68 4	0.001

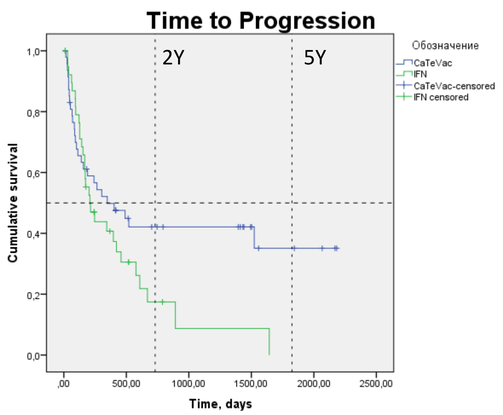
Dosing

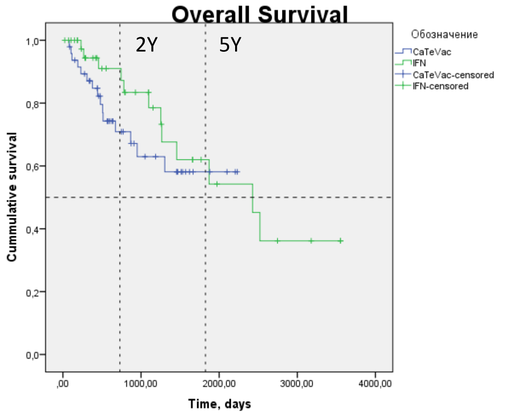
	N
CaTeVac - 5-15*10^6 mature DC cells:	48
IFN:	
• High Dose:	2
• Low Dose (3-5 MIU):	36
• Dose escalation to until maximum tolerated dose achieved:	4

Time to progression (TTP) – from surgery to the first signs of disease progression or death from disease progression.
Overall survival (OS) – from surgery to death from any cause.

RESULTS

Survival	CaTeVAC	IFN	p
TTP, median, mo.	11,4	6,9	0,097
2-year (2Y) TTP, %	42	17	
5-year (5Y) TTP, %	35	0	
Relative risk of progression in 2 years (95% CI)	0,74 (0,57-0,96)	1	
OS median, mo	Not reached	61.5	0.635
2-year (2Y) OS, %	71	83	
5-year (5Y) OS, %	58	54	





CONCLUSION

Rather promising results received in our study justify performing of randomized trials with CaTeVac and IFN in adjuvant setting for patients with melanoma.

Presenter

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